

10/579.088

Manzer Durrani, et al.

Group Art Unit:
1646

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CK/

Form PTO-1449	Attorney's Docket No. ARR-0036	Application Serial No. 10/579,088
INFORMATION DISCLOSURE STATEMENT	Applicant(s) Manzer Durrani, et al.	

(use several sheets if necessary)	Filing Date: January 14, 2008	Group Art Unit: 1646
-----------------------------------	----------------------------------	-------------------------

FOREIGN PATENT DOCUMENTS									
Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Translation		
							YES	NO	
	34.	11/22/1984	WO 1984/04538	WO					
	35.	06/27/2002	WO 2002/50287	WO					
	36.	12/27/1990	EP 73,654 A	EP					
	37.	09/28/1988	EP 0 284 044 A1	EP					
	38.	06/27/2002	WO 02/50287	WO					
	39.	10/17/1996	WO 96/32152	WO					
	40.	04/23/1998	WO 98/16205	WO					
	41.	09/21/2000	WO 00/54797	WO					
	42.	07/22/2004	WO 2004/060528	WO					
	43.	07/31/2002	EP 0 648 838	EP					
	44.	10/02/2002	EP 1 047 450	EP					
	45.	07/31/2002	EP 1 226 136	EP					
	46.	06/15/2000	WO 00/34237	WO					
	47.	07/11/2002	WO 02/053138	WO					
	48.	08/22/2002	WO 02/064080	WO					
	49.	08/21/2003	WO 03/068188	WO					
	50.	09/18/2003	WO 03/075959	WO					
	51.	07/01/1999	WO 2004/103364	WO					
	52.	01/13/2005	WO 2005/003150	WO					
	53.	06/11/1992	WO 92/09282	WO					
	54.	06/11/1992	WO 92/09556	WO					
	55.	06/11/1992	WO 92/09563	WO					
	56.	07/22/1993	WO 93/13741	WO					
	57.	02/03/1994	WO 94/02446	WO					
	58.	09/29/1994	WO 94/21625	WO					
	59.	10/13/1994	WO 94/22309	WO					
	60.	04/13/1995	WO 95/09841	WO					
	61.	07/27/1995	WO 95/19965	WO					
	62.	05/30/1996	WO 96/16027	WO					
	63.	11/13/1997	WO 97/42168	WO					
	64.	2/26/1998	WO 98/07742	WO					
	65.	04/09/1997	WO 98/14424	WO					
	66.	10/8/1998	WO 98/43946	WO					
	67.	10/29/1998	WO 98/47863	WO					
	68.	09/10/1999	WO 99/44989	WO					
	69.	07/01/1999	WO 99/32150	WO					

EXAMINER:	DATE CONSIDERED:
<p>EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.</p> <p>*If an asterisk is placed beside the reference number, a copy is not provided because the reference was previously cited by or submitted to the PTO in a prior application that is identical in the statement and relied upon for an earlier filing date under 35 U.S.C. §120. 37 C.F.R. §1.98 (d).</p>	

Form PTO-1449 INFORMATION DISCLOSURE STATEMENT			Attorney's Docket No. ARR-0036		Application Serial No. 10/579,088	
			Applicant(s) Manzer Durrani, et al.			
(use several sheets if necessary)			Filing Date: January 14, 2008		Group Art Unit: 1646	
70.		07/31/2002	EP 1 226 119		EP	
OTHER DOCUMENTS (including author, title, date, pertinent pages, etc.)						
Examiner Initials	Ref. No.	Title				
	71.	Benetzen, et al., "Codon Selection in Yeast," The Journal of Biological Chemistry, 257(6): 3026-3031, 1982.				
	72.	Tamer, et al., "Production and Recovery of Recombinant Protease Inhibitor Alpha-1-Antitrypsin, Enzyme and Microbial Technology," 29: 611-620, 2001.				
	73.	Russell, et al., "Nucleotide Sequence of the Yeast Alcohol Dehydrogenase II Gene," The Journal of Biological Chemistry, 258(4): 2674-2682, 1983.				
	74.	Barr, et al., "Yeast Genetic Engineering," Chap. 6, Butterworths, 1989.				
	75.	Broach, et al., "Transformation in Yeast: Development of a Hybrid Cloning Vector and Isolation of the CAN1 Gene," Gene, 8:121-133, 1979.				
	76.	Pearson, et al., "Improved Tools for Biological Sequence Comparison," Proceedings of the National Academy of Science, 85: 244-248, 1988.				
	77.	Tuite, M.F., et al., "Regulated High Efficiency Expression of Human Interferon-Alpha in Saccharomyces cerevisiae," The EMBO Journal, 1(5): 603-608, 1982.				
	78.	Kurachi, K., et al., "Cloning and Sequence of cDNA Coding for α -1-Antitrypsin," Proc Natl Acad Sci USA, Biochemistry, 78(11): 6826-6830, 1981.				
	79.	Kurjan, J., et al., "Structure of a Yeast Pheromone Gene (MF α): A Putative α -Factor Precursor Contains Four Tandem Copies of Mature α -Factor," Cell, 30: 933-943, 1982.				
	80.	Zakian, V.A., et al., "Construction, Replication, and Chromatin Structure of TRP1 R1 Circle, a Multiple-Copy Synthetic Plasmid Derived from Saccharomyces cerevisiae Chromosomal DNA", Molecular and Cellular Biology, 2(3): 221-232, 1982.				
	81.	Dayhoff, et al., "A Model of Evolutionary Change in Proteins," Atlas of Protein Sequence and Structure, National Biomedical Research Foundation, 5(3):345-358, 1979.				
	82.	Hein, J., "Unified Approach to Alignment and Phylogenies," Methods in Enzymology, 183: 626-645, 1990.				
	83.	Higgins, D.G., et al., "Fast and Sensitive Multiple Sequence Alignments on a Microcomputer," CABIOS Communications, 5(2): 151-153, 1989.				
	84.	Jones, E.W., "Vacuolar Proteases in Yeast Saccharomyces Cerevisiae," Methods in Enzymology, 85(31):372-386, 1990.				
	85.	Kurtz, M.B., et al., "Integrative Transformation of Candida albicans, Using a Cloned Candida ADE2 Gene," Molecular and Cellular Biology, 6(1): 142-149, 1986.				

EXAMINER:	DATE CONSIDERED:
<p>EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.</p> <p>*If an asterisk is placed beside the reference number, a copy is not provided because the reference was previously cited by or submitted to the PTO in a prior application that is identical in the statement and relied upon for an earlier filing date under 35 U.S.C. §120. 37 C.F.R. §1.98 (d).</p>	

Form PTO-1449

INFORMATION DISCLOSURE STATEMENT

Attorney's Docket No.

ARR-0036

Application Serial No.

10/579,088

Applicant(s)

Manzer Durrani, et al.

(use several sheets if necessary)

Filing Date:

January 14, 2008

Group Art Unit:

1646

86. Kunze, et al., "Transformation of the Industrially Important Yeasts *Candida maltosa* and *Pichia guilliermondii*," *Journal of Basic Microbiology*, 25(2): 141-144, 1984.
87. Myers, E.W., et al. "Optimal Alignments in Linear Space," *CABIOS Communications*, 4(1): 11-17, 1988.
88. Robinson, D.F., "Comparison of Labeled Trees with Valency Three," *Journal of Combinatorial Theory*, 11: 105-119, 1971.
89. Saitou, N., et al., "The Neighbor-Joining Method: A new Method for Reconstructing Phylogenetic Trees," *Molecular Biology and Evolution*, pp. 406-425, 1987.
90. Wilbur, W.J., et al., "Rapid Similarity Searches of Nucleic Acid and Protein Data Banks," *Proc Natl Acad of Sci USA*, 80: 726-730, 1983.
91. Zou, et al., "Maspin, a Serpin with Tumor-Suppressing Activity in Human Mammary Epithelial Cells," *Science*, 263: 526-529, 1994.
92. Gleeson, M.A., et al., "Transformation of the Methylophilic Yeast *Hansenula polymorpha*," *Journal of General Microbiology*, 132: 3459-3465, 1986.
93. Roggenkamp, R., et al., "Transformation of the Methylophilic Yeast *Hansenula polymorpha* by Autonomous Replication and Integration Vectors," *Mol. Gen. Genet.*, 202: 302-308, 1986.
94. Das, et al., "Transformation of *Kluyveromyces fragilis*," *Journal of Bacteriology*, 158(3): 1165-1167, 1984.
95. De Louvencourt, et al., "Transformation of *Kluyveromyces lactic* by Killer Plasmid DNA," *Journal of Bacteriology*, 154(2): 737-742, 1983.
96. Van Den Berg, et al., "Kluyveromyces as a Host of Heterologous Gene Expression: Expression and Secretion of Prochymosin," *Biotechnology*, 8: 135-140, 1990.
97. Cregg, et al., "Pichia Pastoris as a Host System for Transformations," *Molecular and Cellular Biology*, 5(12): 3376-3385, 1985.
98. Hinnen, A., et al., "Transformation of Yeast," *Proc. Natl. Acad. Sci. USA, Genetics*, 75(4): 1929-1933, 1978.
99. Ito, H., et al., "Transformation of Intact Yeast Cells Treated with Alkali Cations," *Journal of Bacteriology*, 153(1): 163-168, 1983.
100. Davidow, L.S., et al., "Integrative Transformation of the Yeast *Yarrowia lipolytica*," *Current Genetics*, 10: 39-48, 1985.
101. Gallardin, et al., "Integrative transformation of the Yeast *Yarrowia lipolytica*," *Current Genetics*, 10: 49-58, 1985.
102. Winkler, M., "Time-Profiling and Environmental Design in Computer -Controlled Fermentation and Enzyme Production,"

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

*If an asterisk is placed beside the reference number, a copy is not provided because the reference was previously cited by or submitted to the PTO in a prior application that is identical in the statement and relied upon for an earlier filing date under 35 U.S.C. §120. 37 C.F.R. §1.98 (d).

Form PTO-1449		Attorney's Docket No. ARR-0036	Application Serial No. 101579,088
INFORMATION DISCLOSURE STATEMENT		Applicant(s) Manzer Durrani, et al.	
(use several sheets if necessary)		Filing Date: January 14, 2008	Group Art Unit: 1646
	Genetically-Engineered Proteins and Enzymes from Yeast: Production Control, Ellis Horwood Limited, Chp. 4 and 5, pp. 96-184, 1991.		
103.	Schiestl, et al., "High Efficiency Transformation of Intact Yeast Cells Using Single Stranded Nucleic Acids as a Carrier," Current Genetics, 16: 339-346, 1989.		
107.	Jones, E.W., "Tackling the Protease Problem in Saccharomyces Cerevisiae," Methods in Enzymology, 194: 428-453, 1991.		
105.	du Preez, J.C., et al., "Transcriptional Repression of ADH2-Regulated β -xylanase Production by Ethanol in Recombinant Strains of Saccharomyces Cerevisiae," FEMS Yeast Research, 1: 233-240, 2001.		
106.	European Search Report dated January 9, 2007.		
107.	Kaslow, D.C., et al., "Production, Purification and Immunogenicity of a Malaria Transmission-Blocking Vaccine Candidate: TBV25H Expressed in Yeast and Purified Using Nickel-NTA Agarose," Nature Publishing Group, 12: 494-499, 1994.		
108.	Noronha, S.B., et al., "Transition Phase in the Production of Recombinant Proteins in Yeast Under the ADH2 Promoter: An Important Step for Reproducible Manufacturing of a Malaria Transmission Blocking Vaccine Candidate," Journal of Individual Microbiology & Biotechnology, 20: 192-199, 1993.		
109.	O'Connor, G.M., "Design and Evaluation of Control Strategies for High Cell Density Fermentations," Biotechnology and Bioengineering, 39 (3): 293-304, 1992.		
110.	Sabin, E.A., et al., "High-Level Expression and in Vivo Processing of Chimeric Ubiquitin Fusion Proteins in Saccharomyces Cerevisiae," BioTechnology, 7: 705-709, 1989.		
111.	Amiali, et al., "High Nisin Z Production by Lactococcus Lactis UL719 in Whey Permeate with Aeration," World Journal of Microbiology & Biotechnology, 14: 887-894, 1998.		
112.	Beatty, et al., "Kinetics of Association of Serine Proteinases with Native and Oxidized Alpha-1-Proteinase Inhibitor and Alpha-1-Antichymotrypsin," J. Biol. Chem., 255(9): 3931-3934, 1980.		
113.	Vemuri, et al., "Stability and Characterization of Protein and Peptide Drugs: Case Histories," Wang and Pearlman, Plenum Press, NY, Chap. 9 pp. 263-285, 1993.		
114.	Vemuri, S., et al., "Effect of Cryoprotectants on Freezing, Lyophilization, and Storage of Lyophilized Recombinant Alpha1-Antitrypsin Formulations," PDA Journal of Pharmaceutical Science and Technology, 48(5): 241-246, 1994.		
115.	Pemberton, P., et al., "Inhaled recombinant Alpha 1-Antitrypsin Ameliorates Cigarette Smoke-Induced Emphysema in the Mouse," COPD: Journal of Chronic Obstructive Pulmonary Disease, 3: 101-108, 2006.		
116.	Stockley, et al., "Therapeutic Efficacy of Alpha-1 Antitrypsin (AAT) Augmentation Therapy on the Loss of Lung Tissue: An Integrated Analysis," European Respiratory Society, Abstract, 2008.		
117.	Stolk, et al., "Progression Parameters for Emphysema: A Clinical Investigation," Respiratory Medicine, 101: 1924-1930, 2007.		
118.	Hercz, A., "Proteolytic Cleavages in Alpha-One Antitrypsin and Microheterogeneity," Biochem. Biophys. Res. Comm., 128(1): 199-203, 1985.		
119.	Schasteen, C.S., et al., "Synthetic Peptide Inhibitors of Complement Serine Proteinases - Significant Increase in Inhibitor		

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

If an asterisk is placed beside the reference number, a copy is not provided because the reference was previously cited by or submitted to the PTO in a prior application that is identical in the statement and relied upon for an earlier filing date under 35 U.S.C. §120. 37 C.F.R. §1.98 (d).

Form PTO-1449		Attorney's Docket No. ARR-0036	Application Serial No. 10/579,088
INFORMATION DISCLOSURE STATEMENT		Applicant(s) Manzer Durrani, et al.	
(use several sheets if necessary)		Filing Date: January 14, 2008	Group Art Unit: 1646
	Potency Provides Further Support for the Functional Equivalence Hypothesis," <i>Molecular Immunology</i> , 28(1/2): 472-479, 1991.		
120.	Churg, et al., "Proteases and Emphysema," <i>Current Opinion in Pulmonary Medicine</i> , 11: 153-159, 2005.		
121.	Huang, et al., "Expression and Purification of Functional Human Alpha1-Antitrypsin from Cultured Plant Cells," <i>Biotechnology Prog.</i> , 17: 126-33, 2001.		
122.	Rabe, "Outcome Measures in COPD," <i>Primary Care Respiratory Journal</i> , 13: 177-178, 2004.		
123.	Rosenerg, et al., "Synthesis in Yeast of a Functional Oxidation-Resistant Mutant of Human Alpha1-Antitrypsin," <i>Nature</i> , 312: 77-80, 1984.		
124.	Shapiro, "Envolving Concepts in the Pathogenesis of Chronic Obstructive Pulmonary Disease," <i>Clinics in Chest Medicine</i> , 21(4):621-632, 2000.		
125.	Travis, et al., "Isolation and Properties of Recombinant DNA Produced Variants of Human Alpha1-Proteinase Inhibitor," <i>Journal of Biological Cheimstry</i> , 260(7): 4384-4389, 1985.		
126.	Terashima, et al., "Production of Functional Human Alpha1-Antitrypsin by Plant Cell Culture," <i>Appl. Microbiol. Biotechnol.</i> , 52: 516-523, 1999.		
127.	Barnes, P.J., "Novel Approaches and Targets for Treatment of Chronic Obstructive Pulmonary Disease," <i>Am.J. Respir. Crit. Care Med.</i> , 160:S72-S79, 1999.		
128.	Roche, N., et al., "Current Issues in the Management of Chronic Obstructive Pulmonary Diseases," <i>Respirology</i> , 2: 215-229, 1997.		
129.	He, J.Q., et al., "Pharmacogenomics of COPD," <i>Current Pharmacogenomics</i> , 1(4): 229-243, 2003.		
130.	Hubbard, R.C., et al., "Anti-Neutrophil-Elastase Defenses of the Lower Respiratory Tract in Alpha 1-Antitrypsin Deficiency Directly Augmented with an Aerosol of Alpha 1-Antitrypsin," <i>Annals of Internal Medicine</i> , 111(3): 206-212, 1989.		

EXAMINER:	/Claire Kaufman/	DATE CONSIDERED:	06/25/2010
EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.			
*If an asterisk is placed beside the reference number, a copy is not provided because the reference was previously cited by or submitted to the PTO in a prior application that is identical in the statement and relied upon for an earlier filing date under 35 U.S.C. §120. 37 C.F.R. §1.98 (d).			